

## REMARKS

In the pending Office Action, Examiner Amareld first lodged objections to the drawings and to the abstract. As to the first objection, it is believed that the subject matter of claim 28 is sufficiently disclosed in the text of the specification, and should be considered. However, in order to move this application more quickly to allowance, claim 28 is being cancelled without prejudice to consideration in this or a continuing application. As to the objection to the length of the abstract, a new abstract is being presented with this amendment to overcome the objection. No new matter has been added.

Examiner Amareld has also initially rejected claims 16-33 based on one or more of U.S. Patent No. 5,616,142 to Yuan, U.S. Patent No. 5,718,705 to Sammarco, U.S. Patent No. 2,511,051 to Dzus, and PCT Publication No. WO98/01079 to Dall. Respectfully, it is believed that these references do not show all elements of the pending claims, and therefore reconsideration of the claims and withdrawal of the present rejections is respectfully requested.

Turning first to independent claim 16, the Yuan reference is alleged to anticipate it and its dependent claims 17-21. In response, claim 16 is being amended as indicated above. Support for the amendment is shown in Figures 3 and 4a-4e, among others, and accompanying text. In particular, Figures 3 and 4c show a planar cut perpendicular to the longitudinal axis of plate member 522. The intersection of that plane and the upper surface of plate member 522 is at least one straight line, seen directly beneath washer 542 in the embodiment of Figure 3.

The Office Action's analysis relies on the "receiving piece" 10 of Yuan as the recited plate member in claim 16. The Yuan receiving piece is curved, as shown in its Figures 1 and 2, along its short or width dimension. A cross-section perpendicular to the longitudinal axis of the Yuan device, or in other words an intersection of that cross-sectional plane and an upper surface

of the Yuan device, is curved rather than straight. Yuan's device is shaped in that way because of its use as a means for preventing an intervertebral disk from jutting out from its intended location, as Yuan describes at column 2, lines 14-21. Accordingly, the Yuan device must have a close fit with the curved surfaces of multiple vertebrae. Removing the Yuan curvature would defeat that purpose. Thus, not only does Yuan not show the features of claim 16, one of ordinary skill would not be motivated to change the Yuan reference to create the flat upper surface of claim 16.

Claims 17-21 are allowable due to their dependence from claim 16. Further, at least claim 19 is allowable on its own merit, because the Yuan reference does not show or suggest that the recited lower portion extends along substantially the entirety of the length of the upper portion. Receiving portions 10 and 10', as shown in Yuan's Figure 2, include holes 12 and 12' through which screws are to be placed into bone. The "L-shaped lower grooves (11)" identified in the Office Action must end well in front of those holes so that the items 21 and 21' of Yuan do not interfere with screw placement or adjustment. Changing Yuan to overcome this deficiency is not taught by the reference, and would require substantial structural changes that would change the operation of the reference. Accordingly, Yuan does not anticipate and cannot be made to render obvious claim 19.

Claim 22 was initially rejected as allegedly obvious over a combination of the Yuan reference and the Dall reference. Respectfully, there are several reasons that the rejection of claim 22 should be withdrawn. Initially, it is noted that claim 22 is dependent from claim 16, and thus is allowable on at least that basis. Further, no sufficient motivation to combine the Yuan and Dall references was identified in the Office Action. The only possible discussion of motivation is the conclusory statement that "[i]t would have been obvious . . . to use the bone

plate fasteners, as taught by Dall with the bone plate of Yuan such that it provides the ability to lock the fasteners to the plate and attaché the plate to necessary bony structures.” There is no indication in the Office Action of why one of ordinary skill would decide to use Dall’s subject matter in Yuan. This is critical to a *prima facie* case of obviousness, especially in the present case, because Yuan included screws in its disclosure (Figure 3b) which have an upper thread for engaging the threaded holes of the Yuan device and a lower thread for engaging bone. Thus, Yuan’s disclosed screws are specifically engineered for use with the Yuan device. Not only is there no need for anyone to look elsewhere for screws to use with the Yuan device, but the reference teaches away from other screws, such as Dall’s, that do not engage both bone and a threaded device hole. In order to make a legitimate case of obviousness, the examiner must show the desirability of the combination, or why the person of ordinary skill would use the two references together. MPEP 2143.01(III) (“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination” (case citation omitted)). In this case, no desirability of the combination can be shown.

Moreover, the Yuan and Dall references do not show all elements of claim 22. The Office Action asserts that the split ring 16 of Dall is the claimed washer, and nut 14 of Dall is the claimed nut. However, even if the split ring can be considered a “washer,” the split ring does not have a lower surface adjacent the upper portion of a plate member. Rather, the Dall split ring is forced down into the hole in the Dall plate. Additionally, the nut 14 of Dall does not include a sleeve portion as claimed. Dall notes that its nut 14 has “three pillars 17” that connect upper and lower parts of a housing. The “pillars” fit in “flutes” along a shaft so that the nut can travel along the shaft, but not rotate around it. (See Dall, page 5, line 33 to page 6, line 1.) The thin

pillars 17 of Dall spaced apparently regularly around a cylindrical “housing” do not constitute the common understanding of a sleeve. Further, the pillars are necessary for proper operation of the Dall nut, and filling in the spaces between them would prevent it from operating. Without these features of claim 22, and perhaps others, the combination of Yuan and Dall does not include all aspects of the claim, even if the combination could be considered proper.

Claims 23-29 were also initially rejected as allegedly obvious over the Yuan and Dall references. As already discussed, no sufficient motivation for combining the references is demonstrated in the Office Action. One of ordinary skill would not find it desirable to replace the dual-threaded screws designed for the Yuan device with the screw device of Dall. More directly, importing the nut 14 and split ring 16 of Dall into the Yuan reference would not work, as there is no need for them, and there is no place on the Yuan screws to place the Dall nut and split ring. Indeed, the Office Action relies on Yuan to show “threaded fastening elements” and it relies on Dall to show washers and nuts. The fact is that the alleged washer and nut of Dall cannot be used with the “threaded fastening element” of Yuan without an overhaul of the Yuan screw, the Dall nut/split ring, or both. The combination of the Yuan and Dall references also do not show a kit or a plurality of plate members, as claim 23 recites. For at least these reasons, the rejection of claims 23 and its dependent claims 24-29 should be withdrawn.

Additionally, several of dependent claims 24-29 are allowable over the Yuan and Dall references on their own merit. Claim 24 recites a plurality of washers, and even if the Dall reference’s split ring could be considered a “washer,” it does not show a plurality of them. Claim 25 recites that at least two of the plurality of plate members have different lengths, which is not shown or suggested in either Yuan or Dall. Neither reference shows a non-straight plate member, as recited in claim 26.

As to claim 27, Dall does not show a washer and nut that rotate or translate with respect to each other. As noted at page 5, line 33 through the end of the Dall text and in its figures, the split ring 16 of Dall surrounds the pillars 17 of the nut 14. Pillars 17 are within the “flutes” of a shaft and cannot rotate with respect to the shaft, and split ring 16 expands and contracts as it moves with nut 14 along the shaft. When the split ring is in a hole of the Dall plate, it cannot expand, and is thus locked to the shaft. Thus, however the nut is maneuvered, the split ring goes along with it instead of moving with respect to it. When the nut is translated along the shaft, the split ring goes along, and there is no relative translation between the split ring and the nut. When the split ring is in the plate hole, then shaft, nut and split ring are locked together, and turning the nut also turns the split ring. Relative rotation between the split ring and the nut is thus impossible. Since the Dall reference does not disclose the relative movements between a washer and nut recited in claim 27, the claim is allowable on its own merit.

Independent claim 30 was initially rejected as allegedly anticipated by the Yuan, Sammarco and Dzus references. Taking first the Yuan reference, the Office Action asserted that “all circular openings [are] inherently tapered at each edge, additionally the threaded portion providing additional tapered sections.” However, “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities.’ ” MPEP 2112(IV) (case citation and internal quotations omitted). Thus, “the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Id.* (case citation and internal quotations omitted, emphasis in original). The Office Action does not assert or prove

that a taper necessarily flows from a hole, or that one of ordinary skill would recognize it. There is no fact or reasoning supplied in the Office Action to support the inherency conclusion in the Office Action.

A hole with a tapered section is also not explicitly shown in the Yuan reference. There is no evidence from the drawings that the holes taper at any part, and the text likewise gives no indication of any tapering. In fact, the drawings show cylindrical holes 12 and 12' with sharp edges, and the upper threaded part 32 of screw 30 of Yuan is also cylindrical. Because there is insufficient support for the position that "all circular holes are inherently tapered," and because Yuan does not inherently or explicitly show or suggest tapered holes, claim 30 is not anticipated.

Claims 32 and 33 are dependent from claim 30, and are thus also not anticipated by the Yuan reference. Further, Yuan does not show a body lower surface that is convex. The Office Action does not state what is considered to be a "body" in the Yuan reference, and thus the anticipation analysis lacks a vital part of the analysis. Items 10 or 20 of Yuan appear to be the only items that could possibly be compared to the claimed body, and neither have a lower convex surface. Rather, both items 10 and 20 of Yuan have undersides, i.e. sides adjacent groove 11, that are concavely curved. The concave curvature is necessary, as noted above, so that the Yuan device can fit closely to the convex exterior of vertebrae and prevent an intervertebral disk from jutting out. For at least this reason, claim 32 is also allowable on its own merit over Yuan.

The Office Action also asserted that the Sammarco reference anticipated claims 30-33. However, this rejection also relies on the alleged inherency in circular openings of a tapered edge. As demonstrated above, the burden of proof in demonstrating inherency has not been met, and there is no inherent or explicit disclosure in the Sammarco reference itself that hole 15 is

tapered. From the drawings, as in the Yuan drawings, hole 15 of Sammarco appears cylindrical with sharp edges, and there is no basis for conjecturing that one of ordinary skill in the art would see it otherwise.

Moreover, the Office Action does not apply the proper anticipation analysis between the Sammarco reference and claims 30-33. It is axiomatic that, to anticipate, a reference must show all elements of a claim, arranged as the claim describes. See MPEP 2131. Sammarco does not show an octagonal item, i.e. a polygon or bounded figure having eight sides, but a circular central plate 2 with extending arms. Respectfully, it cannot legitimately be suggested that one of ordinary skill would consider an eight-armed or eight-pronged item to be “octagonal.”

Sammarco also does not show or suggest the claimed convex lower surface. Only two figures in Sammarco, figures 15 and 17, show the Sammarco plate and or its constituent fingers bent, and in both cases the bend(s) result in a concave underside. The concave nature of the underside is, as in Yuan, dictated by the necessity of a close fit between the plate/fingers and bone tissue. Whether the Sammarco plate can possibly be configured to have a convex lower surface is not material to this anticipation analysis, and in any event is not taught by the reference. Because Sammarco does not inherently or explicitly show a tapered hole, an octagonal body, or a convex lower surface, it cannot anticipate claims 30-33.

The Office Action further suggested that “clip” 30 of the Dzus reference would anticipate claims 30, 32 and 33. The “prongs” 31 of clip 30 extend down from the clip, that is, along an axis of hole 32, so that they can be inserted into bone tissue, as seen in figure 9 of Dzus. Thus, Dzus does not show at least one or more fingers extending away from a hole axis, as claims 30 and 33 recite. One of ordinary skill would not be motivated to modify the Dzus prongs into that configuration, given the requirement that they extend downward to engage bone. As to claim 32,

the Dzus clip does not have a convex lower surface. Just as noted above with respect to the Sammarco and Yuan references, Dzus' clip has a concave lower surface that is required for close fit to bone, as shown in the figures. For at least these reasons, Dzus does not anticipate or render obvious any of claims 30-33.

Claim 28 is properly supported by the specification of this application. However, as previously noted, claim 28 is being cancelled without prejudice to reconsideration in this or a continuing application. No admission is made as to the objections to or rejections of claim 28.

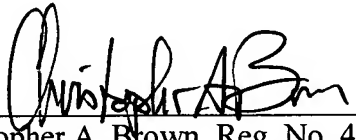
New claims 34-36 are being added to this application. Claim 34 includes the subject matter of original claim 19. Claims 35 and 36 include the subject matter of original claims 16 and 19, respectively, along with additional language concerning the hole in the plate member. Support for claims 35 and 35 is found in Figures 2, 4a, and 4d, among others, and their associated text. No new matter has been added.

It should be understood that the above amendments and remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion. Further, it is believed that no narrowing amendments have been made, and thus the claims should be entitled to the entire scope permitted by their language, including equivalents.



In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is requested. If the Examiner feels that any issues remain, the Examiner is invited to contact the Applicant's undersigned representative by telephone.

Respectfully submitted,

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